

**REMARKS**

Claims 18 and 24-32 are pending in the application and are under active consideration.  
Claims 18, 24-26, and 28-31 have been amended.

Claim 18 has been amended to recite a method for screening chemical compounds comprising the additional step of comparing binding of the HCV receptor to the E2 protein in the presence and absence of a chemical compound to determine if binding is reduced in the presence of the chemical compound indicating that the compound competes with hepatitis C virus for binding to the HCV receptor. Support for the amendment can be found in the specification, for example, at page 1, lines 10-12; page 4, lines 19-21; page 8, lines 34-38; and pages 13-15, which describe methods of screening for chemical compounds that compete with E2 for binding to a HCV receptor and assays for measuring binding.

In order to expedite prosecution, claim 28 has been amended to recite a method for screening for chemical compounds that bind to a HCV receptor, comprising measuring the binding of a chemical compound to said HCV receptor.

In order to expedite prosecution, claims 18 and 28 have been amended to remove the recitation of receptor fragments.

In order to expedite prosecution, claims 24-26 and claims 29-31 have been amended to recite that the claimed methods use human or chimpanzee cells. Support for the amendments can be found in the specification, for example, at page 9, lines 28-29.

In order to expedite prosecution, claims 25 and 30 have been amended to recite a MOLT-4 cell that hyperexpresses the 24 kd protein. In addition, claims 26 and 31 have been amended to recite a cell derived from a MOLT-4 cell that hyperexpresses the 24 kd protein. Support for these amendments can be found in the specification, for example, at page 20, lines 15-19.

The present amendments do not introduce new issues, and place the subject application in condition for allowance and/or simplify issues for appeal. Accordingly, entry of the amendments is proper and respectfully requested.

Cancellation and amendment of the claims is made without prejudice, without intent to abandon any originally claimed subject matter, and without intent to acquiesce in any rejection of record. Applicants expressly reserve the right to file one or more continuing applications hereof containing the canceled or unamended claims.

**Rejection under 35 U.S.C. § 112, second paragraph**

Claims 18, 21-23, and 28-32 have been rejected under 35 U.S.C. § 112, second paragraph, as allegedly being “indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.” (Final Office Action, pages 2-4).

Claims 18 and 21-23 have been rejected under 35 U.S.C. § 112, second paragraph, as allegedly “being incomplete for omitting essential steps, such omission amounting to a gap between the steps.” (Final Office Action, page 2). In particular, the Final Office Action alleges [t]he omitted step is a method indicating how the ability to bind to the 24kd protein relates to the compounds ability to bind to HCV.” (Final Office Action, page 2). Applicant submits that the Final Office Action has confused competitive inhibition of binding to the HCV receptor with binding to HCV. Applicant respectfully points out that the chemical compounds compete with E2 for binding to the HCV receptor. In order to expedite prosecution, Applicant has amended claim 18 to recite the additional step of “comparing the binding of said HCV receptor to the E2 protein in the presence of said chemical compound to the binding of said HCV receptor to the E2 protein in the absence of said chemical compound, wherein reduced binding of said HCV receptor to the E2 protein in the presence of said chemical compound is indicative of a chemical compound that competes with hepatitis C virus for binding to the HCV receptor.” Support for the amendment to claim 18 can be found in the specification, for example, at page 1, lines 10-12; page 4, lines 19-21; page 8, lines 34-38; and pages 13-15, which describe methods of screening for chemical compounds that compete with E2 for binding to the HCV receptor and assays for measuring binding. This amendment further clarifies the intended subject matter of the claimed invention.

In addition, claims 28-32 are similarly rejected on the grounds that allegedly “while the claims provide for a step of measuring the binding of the compound to the 24 kd protein, the claims do not provide for a step associating the results of such measurement of the ability of the compound to compete with HCV, or for identification of the compound as a mimic” (Final Office Action, page 3). The Final Office Action further alleges that “[i]t is unclear if the claims are directed to the identification of compounds that structurally mimic the HCV structure or if the claims require the identification of compounds that mimic the HCV structure only in that

they also bind to the 24 kd protein" (Final Office Action, page 3). In order to expedite prosecution, claim 28 has been amended to recite a method for screening for chemical compounds that bind to a HCV receptor. Therefore, no further step is necessary in the claim, and withdrawal of the rejection under 35 U.S.C. § 112, second paragraph on this basis is respectfully requested.

Claims 28-32 are also rejected under 35 U.S.C. § 112, second paragraph as allegedly being indefinite "[b]ecause the art indicates that there are more than one HCV receptors, it is not clear what is meant by the phrase 'the HCV receptor' (Final Office Action, page 4). In order to expedite prosecution, Applicant has amended claim 28 to recite "a HCV receptor." The claim, as amended, further clarifies that the HCV receptor is "an unglycosylated, transmembrane protein having a molecular weight of about 24 kd as determined by SDS PAGE and which binds to the E2 protein of hepatitis C virus wherein said protein is stable to acetone precipitation." Thus, the HCV receptor recited in claim 28 is the 24 kd protein described throughout the specification and clearly defined based on measurable properties. Therefore, withdrawal of the rejection under 35 U.S.C. § 112, second paragraph of claims 28-32 on this basis is respectfully requested.

For at least the above reasons, Applicant respectfully requests that the rejection under 35 U.S.C. § 112, second paragraph be withdrawn.

#### **Enablement Rejection under 35 U.S.C. § 112, first paragraph**

Claims 18 and 24-28 have been rejected under 35 U.S.C. § 112, first paragraph, on the grounds that the specification does not provide an enabling disclosure commensurate in scope with the claims.

In particular, the Final Office Action alleges that "the specification, while being (for the purposes of this rejection) enabling for the claimed methods wherein the protein to which binding is being screened is the 24kd protein that binds to the HCV E2 protein, does not reasonably provide enablement for methods using any 'functionally equivalent' or fragment thereof" (Final Office Action, page 4). Applicant does not concede to the Patent Office position; however, in the interest of expediting prosecution, claims 18 and 28 have been amended to remove the recitation of fragments.

In addition, the Final Office action alleges that “the specification, while being enabling for methods of identifying compounds that bind to the 24kd protein, does not reasonably provide enablement for methods of identifying compounds that compete with HCV for binding to any host cell receptor” (Final Office Action, page 7). Applicant does not concede to the Patent Office position; however, in the interest of expediting prosecution, claim 18 has been amended to recite a method for screening chemical compounds for ability to compete with HCV for binding to a HCV receptor.

Further, the Final Office Action alleges that “[t]here is no indication that any compound that binds to the 24 kd protein would necessarily compete with HCV binding to the same protein. Additionally, there are no teachings in the application as to which portions of the 24 kd protein are actually targeted by HCV such that those in the art would be able to determine if a compound identified by the claimed method binds to the same, or an overlapping region of the 24 kd protein such that it would compete with HCV binding” (Final Office Action, pages 7-8). Applicant respectfully traverses the rejection on the following grounds.

Claim 18, as currently amended, recites a method comprising the additional step of comparing the binding of said HCV receptor to the E2 protein in the presence of said chemical compound to the binding of said HCV receptor to the E2 protein in the absence of said chemical compound, wherein reduced binding of said HCV receptor to the E2 protein in the presence of said chemical compound is indicative of a chemical compound that competes with hepatitis C virus for binding to the HCV receptor. Support for this amendment can be found in the specification, for example, at page 1, lines 10-12; page 4, lines 19-21; page 8, lines 34-38; and pages 13-15, which describe methods of screening for chemical compounds that compete with E2 for binding to a HCV receptor and assays for measuring binding. Knowledge of the precise region of the 24 kd protein that is targeted by HCV is not necessary to determine if a compound competitively inhibits binding of HCV to the 24 kd protein. One of skill in the art can readily measure reduced binding of E2 to a HCV receptor as a function of increasing concentration of a chemical compound. For example, the specification describes the use of FACS binding assays for measuring binding of E2 to a HCV receptor on a cell and for determining factors influencing binding (see, e.g., page 16, lines 13-23 and 36-38). Therefore, the claimed method of screening

chemical compounds for ability to compete with hepatitis C virus for binding to a HCV receptor is adequately enabled.

Finally, the Final Office Action alleges that claims 28-32, drawn to methods for screening for chemical compounds that mimic the HCV surface structure that binds to a HCV receptor fail to comply with the enablement requirement on the grounds that “[b]ecause there is no identification of the structures that are to be mimicked, the application has not enabled the identification of such mimics” (Final Office Action, page 9). Further, the Final Office Action alleges that the claims “do not provide any means for the determination if the compounds structurally mimic the HCV structure, *i.e.*, there is no step comparing the structure of the HCV surface structure to the structure of the chemical compound” (Final Office Action, page 9). The Examiner acknowledges that a method of identification of chemical compounds that bind to the 24 kd protein is enabled. Claim 28, as currently amended, recites a method for screening for chemical compounds that bind to a HCV receptor. Applicant submits that claim 28, as currently amended, is adequately enabled.

For at least the above reasons, Applicant respectfully requests that the enablement rejection under 35 U.S.C. § 112, first paragraph be withdrawn.

**Written Description Rejection under 35 U.S.C. § 112, first paragraph**

Claims 18, 24-25, and 28-30 have been rejected under 35 U.S.C. § 112, first paragraph for alleged lack of an adequate written description. In particular, the Final Office Action alleges that “the application does not provide any structural identification of the truncated proteins that may be used” (Final Office Action, page 6). In addition, the Final Office Action alleges that the application provides support for the isolation and use only of 24 kd proteins from humans and chimpanzees, and not from any mammal” (Final Office Action, page 6). The Final Office Action further alleges that “the application does not provide adequate support for claims drawn to methods of isolating the protein from any cell that hyperexpresses it, because there is insufficient support for that genus of cells” (Final Office Action, pages 6-7).

Applicant does not concede to the Patent Office position; however, in the interest of expediting prosecution the following amendments have been made:

HCV Receptor Fragments

Claims 18 and 28 have been amended to remove the recitation of receptor fragments.

Mammalian Cells

Claims 24-26 and claims 29-31 have been amended to recite that the claimed methods use human or chimpanzee cells. Support for the amendments can be found in the specification, for example, at page 9, lines 28-29.

Cells that Hyperexpress HCV Receptor

Claims 25 and 30 have been amended to recite a MOLT-4 cell that hyperexpresses the 24 kd protein. In addition, claims 26 and 31 have been amended to recite a cell derived from a MOLT-4 cell that hyperexpresses the 24 kd protein. Support for these amendments can be found in the specification, for example, at page 20, lines 15-19.

For at least the above reasons, Applicant respectfully requests that the written description rejection under 35 U.S.C. § 112, first paragraph be withdrawn.

CONCLUSION

In light of the above remarks, Applicant submits that the present application is fully in condition for allowance. Early notice to that effect is earnestly solicited.

If the Examiner contemplates other action, or if a telephone conference would expedite allowance of the claims, Applicant invites the Examiner to contact the undersigned.

The Commissioner is hereby authorized to charge any fees and credit any overpayment of fees which may be required under 37 C.F.R. §1.16, §1.17, or §1.21, to Deposit Account No. 18-1648.

Please direct all further written communications regarding this application to:

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Respectfully submitted,

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